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REMARKS

Claims 38-45, 51-98, 101, 106-109, and 129-135 were pending. By way of the present amendment, Claims 38, 101 and 132 are amended; therefore Claims 38-45, 51-98, 101, 106-109, and 129-135 remain pending for consideration.

Claims 95-98

Although Claims 95-98 are pending in the present application, the Office Action cover sheet does not indicate this status. Claims 95-98 are still pending in the present application, and are patentable for the reasons provided below. The Applicants respectfully request that Claims 95-98 be allowed for the reasons indicated below.

Rejection of Claims 38-45, 51-98, 101, 106-109, and 129-135 under 35 U.S.C. § 103(a)

Claims 38-45, 51-94, 101, 106-109, and 129-135 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Huebsch, et al., U.S. Patent No. 5,853,422 ("Huebsch") in view of Banas, et al., U.S. Patent No. 6,124,523 ("Banas"). Claims 95-98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Huebsch in view of Banas, and further in view of Riedy, et al., U.S. Patent No. 5,108,474 ("Riedy").

Claims 38-45 and 61-76

Claim 38 has been amended to recite, inter alia, a containment device for positioning at a left atrial appendage, comprising: a proximal end, a distal end, an intermediate portion between the proximal and distal ends, and a longitudinal axis extending therethrough; at least three supports extending between the proximal end and the distal end; each support comprising an elongate, flexible element which is movable from a first orientation in which the element extends substantially parallel to the axis at no more than a first distance from the axis, to a second orientation in which at least a portion of the element is inclined toward the intermediate portion with respect to the axis and is separated by at least a second distance from the axis which is greater than the first distance, wherein the intermediate portion in the second orientation is sized and configured to engage a surface at the left atrial appendage and the supports in their second orientation increase radially in dimension from the proximal end to an apex portion and then decrease radially in dimension from the apex portion to the distal end; and an endothelialization membrane carried by the device, for promoting endothelialization across the left atrial

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appendage, wherein the endothelialization membrane at least in part comprises a first membrane on a first side of the supports, a second membrane on a second side of the supports, and a bonding layer for bonding the first membrane and the second membrane together.

Neither Huebsch, Banas, nor the combination thereof teaches or suggests, inter alia, a containment device comprising at least three supports movable from a first orientation in which the element extends substantially parallel to the axis at no more than a first distance from the axis, to a second orientation in which at least a portion of the element is inclined toward the intermediate portion with respect to the axis and separated by at least a second distance from the axis which is greater than the first distance, wherein the supports in their second orientation increase radially in dimension from the proximal end to an apex portion and then decrease radially in dimension from the apex portion to the distal end.

In contrast, Huebsch teaches a septal defect closure device 10, 200 having hinge points 24, 225 that move radially away from the axis of the device in a hinge-like fashion in response to the movement of proximal ends 14, 214 and distal ends 16, 216 toward a central portion 18, 218 of the device 10, 200. See, Huebsch, col. 4, ll. 28-32; col. 6, ll. 54-57.

Because the references cited by the Examiner do not disclose, teach or suggest, inter alia, supports in their second orientation increasing radially in dimension from the proximal end to an apex portion and then decreasing radially in dimension from the apex portion to the distal end, the Applicants assert that Claim 38 is not obvious in view of Huebsch and Banas, and furthermore, that even if one were to combine Huebsch and Banas, such a combination would not teach all of the elements of Claim 38. The Applicant therefore respectfully submits that Claim 38 is patentably distinguished over the cited references and the Applicant respectfully requests allowance of Claim 38.

Section 2143 of the M.P.E.P. states that to establish prima facie obviousness three requirements must be met:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach

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or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's disclosure.

In the present case, neither the Huebsch nor the Banas reference teach or suggest, inter alia, supports in their second orientation increasing radially in dimension from the proximal end to an apex portion and then decreasing radially in dimension from the apex portion to the distal end. In addition, the Huebsch reference is directed to septal defect closure devices (*e.g.*, devices designed to close openings in the heart), and the Banas reference is directed to encapsulated stents (*e.g.*, devices designed to maintain the opening of a vessel in the body). The Examiner has failed to establish that one of skill in the art looking to build a device for closing openings in the heart would be motivated to combine a reference regarding closing an opening in the heart with a reference regarding keeping vessels open. Furthermore, the Examiner has failed to establish that there would be an expectation of success in doing so. Thus, the Examiner has failed to establish a suggestion or motivation to combine the Huebsch and Banas references. Also, because neither the Huebsch, Banas, nor any other cited reference, teaches teach or suggests supports in their second orientation increasing radially in dimension from the proximal end to an apex portion and then decreasing radially in dimension from the apex portion to the distal end, the Examiner has not provided prior art that if combined, teaches all the claim limitations.

Rather, it appears that the Examiner has impermissibly used hindsight derived from the teachings in the present application, and not the teachings of the prior art, to reject Claim 38. In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999) (holding the Board impermissibly used hindsight in determining obviousness); see also, M.P.E.P., Sect. 2145, part X.A. In Dembiczak, the Federal Circuit reiterated that a determination of obviousness cannot simply rely on the inventor's disclosure as a "blueprint" without evidence of a suggestion, teaching or motivation in the prior art. Dembiczak, 175 F.3d 994, 999. Also, according to M.P.E.P. Section 706.02(j), "[t]he teaching and suggestion to make the claimed combination and the reasonable expectation for success must both be found in the prior art and not based on the Applicant's disclosure." (emphasis added).

The Applicants therefore respectfully submit that Claim 38 is patentably distinguished over the cited references and the Applicants respectfully request allowance of Claim 38.

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Claims 39-45 and 61-76 depend directly or indirectly from Claim 38, and are therefore patentable over the cited art for the same reasons provided above. Claims 39-45 and 61-76 are also patentable for the combination of features disclosed therein.

Claims 51-60, 77-98, 129 and 130

Claim 51 recites a containment device for implantation at an opening in the body, comprising: a support member movable from a reduced cross-section to an enlarged cross-section, the support member in the enlarged cross-section extending from a proximal end and inclining radially outward to an apex portion, and then inclining radially inward to a distal end; and a porous endothelialization membrane carried by the support member, wherein the endothelialization membrane at least in part comprises a first membrane on a first side of the support member, a second membrane on a second side of the support member, and a bonding layer for bonding the first membrane and the second membrane together.

Similar to the discussion above with respect to Claim 38, neither Huebsch, Banas, nor the combination thereof teaches or suggests, inter alia, a containment device comprising a support member movable from a reduced cross-section to an enlarged cross-section, the support member in the enlarged cross-section extending from a proximal end and inclining radially outward to an apex portion, and then inclining radially inward to a distal end.

In addition, for the same reasons discussed above, the Examiner has failed to provide any motivation to combine the Huebsch and Banas references, or identify any reasonable expectation for success, both of which must both be found in the prior art and not based on the Applicants' disclosure.

For at least these reasons, Claim 51 is patentable over the cited art, and the Applicants respectfully request allowance of Claim 51.

Claims 52-60, 77-98, 129, and 130 depend directly or indirectly from Claim 51, and are therefore patentable over the cited art for the same reasons provided above. Claims 52-60, 77-98, 129, and 130 are also patentable for the combination of features disclosed therein.

Claims 101 and 106-109

Claim 101 recites a device for implantation within a left atrial appendage of a patient, the device comprising: an expandable frame having a proximal end, a distal end, and a longitudinal axis extending therethrough, the frame comprising a plurality of supports; each support comprising an elongate, flexible element, at least some of the supports being movable from a

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first orientation in which the element extends substantially parallel to the axis at no more than a first distance from the axis, to a second orientation in which at least a portion of the element is inclined with respect to the axis and is separated by at least a second distance from the axis which is greater than the first distance, wherein the supports in their second orientation increase radially in dimension from the proximal end to an apex portion and then decrease radially in dimension from the apex portion to the distal end; and an endothelialization membrane attached to at least a proximal face of the device having a pore size sufficient to permit endothelialization, the proximal face of the device comprising at least in part the inclined portion of a plurality of the flexible elements and being sized and configured to block an opening to the left atrial appendage; wherein the endothelialization membrane has a porosity in the range of about 5 to about 60 microns.

Similar to the discussion above with respect to Claim 38, neither Huebsch, Banas, nor the combination thereof teaches or suggests, inter alia, a device for implantation within a left atrial appendage of a patient comprising an expandable frame having a plurality of supports, wherein the supports in their second orientation increase radially in dimension from the proximal end to an apex portion and then decrease radially in dimension from the apex portion to the distal end.

In addition, for the same reasons discussed above, the Examiner has failed to provide any motivation to combine the Huebsch and Banas references, or identify any reasonable expectation for success, both of which must both be found in the prior art and not based on the Applicants' disclosure.

For at least these reasons, Claim 101 is patentable over the cited art, and the Applicants respectfully request that the Examiner allow Claim 101.

Claims 106-109 depend directly from Claim 101, and are therefore patentable over the cited art for the same reasons provided above. Claims 106-109 are also patentable for the combination of features disclosed therein.

Claims 131-135

Claim 131 recites a device for implantation within a left atrial appendage of a patient, the device comprising: a frame having a generally cylindrical configuration having a proximal end and a distal end, the frame sized and configured to be positioned at the left atrial appendage; and a membrane provided over and closing off the proximal end of the frame to prevent the passage of embolic material through the frame.

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Neither Huebsch, Banas, nor the combination thereof teaches or suggests, inter alia, a frame having a membrane provided over and closing off the proximal end of the frame to prevent the passage of embolic material through the frame. In Huebsch, there is no teaching or suggestion that the fabric covering close off the proximal end of a frame having a generally cylindrical configuration. Furthermore, Banas teaches an encapsulated stent having a lumen, and useful as a vascular graft. Vascular grafts are typically used to replace or repair damaged or occluded blood vessels within the body. Banas, col. 1, ll. 23-26; col. 3, ll. 13-14. Banas does not teach, inter alia, a frame having a membrane provided over and closing off the proximal end of the frame. In fact, Banas teaches away from closing off the proximal end of an encapsulated stent, for to do so would contradict Banas's "principal objective . . . to provide a reinforced vascular graft in the form of an encapsulated stent" Banas, col. 3, ll. 13-15.

Therefore, even if one were to combine Huebsch and Banas, one would not teach all of the elements of Claim 131.

In addition, the Examiner has failed to provide any motivation to combine the Huebsch and Banas references, or identify any reasonable expectation for success, both of which must both be found in the prior art and not based on the Applicants' disclosure.

For at least these reasons, Claim 131 is patentable over the cited art, and the Applicants respectfully request that the Examiner allow Claim 131.

Claims 132-135 depend directly from Claim 131, and are therefore patentable over the cited art for the same reasons provided above. Claims 132-135 are also patentable for the combination of features disclosed therein.

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CONCLUSION

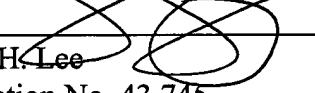
In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants' undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicants' attorney can be reached at (949) 721-6360 or at the number listed below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1-4-05

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